entities. The D–U–N–S number is free and easy to obtain from *http://www.dnb.com/US/duns_update/.*

4. Intergovernmental Review

Executive Order 12372, Intergovernmental Review of Federal Programs, is not applicable to these grant applications.

IV. Application and Submission Information

1. Address To Request Application Package

Application materials can be obtained from *http://www.grants.gov* or *http://www.aoa.gov/doingbus/fundopp/fundopp.asp.*

Application materials are also available by writing to: U.S. Department of Health and Human Services, Administration on Aging, John Murphy, Center for Planning and Policy Development, Washington, DC 20201, Or by calling: 202–357–0136, Or e-mailing: *john.murphy@aoa.hhs.gov.*

2. Address for Application Submission

Electronic submissions must be sent to: *http://www.grants.gov.* Applicants unable to submit their application via *http://www.grants.gov* may request permission to submit a hard copy from the AoA Project Officer: Joseph Lugo, *joseph.lugo@aoa.hhs.gov,* (202) 357–3417.

If you mail or hand deliver your application, you must submit one original application and two copies, plus a completed application checklist to AoA. The application deadline for applications sent by U.S. Postal Service must be postmarked by midnight July 21, 2006 or hand-delivered by 5 p.m. Eastern Time on July 21, 2006.

Submissions using the regular, U.S. Postal Service must be addressed to: Department of Health and Human Services, Administration on Aging, Grants Management Division, Washington, DC 20201, Attention: Stephen Daniels.

Submissions by courier, overnight delivery, delivered in person, etc. should be addressed to: Department of Health and Human Services, Administration on Aging, Grants Management Division, One Massachusetts Avenue, NW., Room 4604, Washington, DC 20001, Attention: Stephen Daniels.

3. Submission Dates and Times

To receive consideration, applications must be received by the deadline listed in the **DATES** section of this Notice.

V. Responsiveness Criteria

Each application submitted will be screened to determine whether it was received by the closing date and time. Applications received by the closing date and time will be screened for completeness and conformity with the requirements outlined in Sections III and IV of this Notice and the Program Announcement. Only complete applications that meet these requirements will be reviewed and evaluated competitively.

VI. Application Review Information

Eligible applications in response to this announcement will be reviewed according to the following evaluation criteria:

- Accomplishments and Problem Statement—Weight: 30 points.
- Approach, Work Plan and Activities—Weight: 40 points.
- Project Outcomes and Evaluation—Weight: 15 points.
- Level of Effort (Organization and Management; Budget and Resources)—Weight: 15 points.

VII. Agency Contacts

Direct inquiries regarding programmatic issues should be sent to: U.S. Department of Health and Human Services, Administration on Aging, Center for Planning and Policy Development, Attention: Joseph Lugo, Washington, DC 20201. Telephone: (202) 357–3417.

Dated: June 14, 2006.

John Wren,

Deputy Assistant Secretary for Management.

[FR Doc. E6–9591 Filed 6–16–06; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Environmental Health/Agency for Toxic Substances and Disease Registry

The Program Peer Review Subcommittee of the Board of Scientific Counselors (BSC), Centers for Disease Control And Prevention (CDC), National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR): Teleconference.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), CDC, NCEH/ATSCR announces the following subcommittee meeting:

Name: Program Peer Review Subcommittee (PPRS).

Time and Date: 10 a.m.–12 p.m. Eastern Daylight Time, June 26, 2006.

Place: The teleconference will originate at NCEH/ATSDR in Atlanta, Georgia. To participate, dial 877/315–6535 and enter conference code 383520.

Purpose: Under the charge of the BSC, NCEH/ATSDR, the PPRS will provide the BSC, NCEH/ATSDR with advice and recommendations on NCEH/ATSDR program peer review. They will serve the function of organizing, facilitating, and providing a long-term perspective to the conduct of NCEH/ATSDR program peer review.

Matters To Be Discussed: A review of the June 8, 2006 PPRS meeting regarding NCEH/ATSDR Director's priorities and vision for the program peer review process; a discussion of NCEH/ATSDR programs and cross-cutting areas and development of revised schedule for peer reviews; a review and revision of Peer Review Questionnaires; and a discussion regarding approaches for obtaining input from partners and customers. Agenda items are subject to change as priorities dictate.

Supplementary Information: This meeting is scheduled to begin at 10 a.m. Eastern Daylight Time. To participate, please dial (877) 315–6535 and enter conference code 383520. Public comment period is scheduled for 11:45–11:55 a.m.

Due to programmatic matters, this **Federal Register** Notice is being published on less than 15 calendar days notice to the public (41 CFR 102–3.150(b)). The program peer review process has a revision deadline for early fall. The Subcommittee must meet to review and deliberate on the NCEH/ATSDR Director's priorities and vision.

For Further Information Contact: Sandra Malcom, Committee Management Specialist, Office of Science, NCEH/ATSDR, M/S E–28, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone 404/498–0622.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and NCEH/ATSDR.

Dated: June 13, 2006.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E6–9562 Filed 6–16–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0040]

Determination of Regulatory Review Period for Purposes of Patent Extension; ROZEREM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ROZEREM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ROZEREM (ramelteon). ROZEREM is indicated for the treatment of insomnia characterized by difficulty with sleep onset. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ROZEREM (U.S. Patent No. 6,034,239) from Takeda Pharmaceutical Co., Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 24, 2006, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ROZEREM represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ROZEREM is 2,224 days. Of this time, 1,920 days occurred during the testing phase of the regulatory review period, while 304 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: June 22, 1999. The applicant claims May 5, 1999, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 22, 1999, when the applicant was notified that the IND studies were allowed to proceed after being on clinical hold.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: September 22, 2004. FDA has verified the applicant's claim that the new drug application (NDA) for Rozerem (NDA 21–782) was initially submitted on September 22, 2004.

3. *The date the application was approved*: July 22, 2005. FDA has verified the applicant's claim that NDA 21–782 was approved on July 22, 2005.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 808 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by August 18, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 18, 2006. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 17, 2006.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E6–9509 Filed 6–16–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0063]

Guidance for Industry and Food and Drug Administration Staff; the Review and Inspection of Premarket Approval Application Manufacturing Information and Operations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations." One of the performance goals, referenced in a letter that accompanied the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) legislation, includes a commitment to improve FDA's scheduling and timeliness of preapproval inspections. This draft guidance document is intended to assist manufacturers in preparing for FDA's review of their premarket approval application (PMA) manufacturing section and in the coordination of the